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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR . | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/620,787 | 07/15/2003 | John Simard | 51300-00006 | 1118 |

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EXAMINER

HURT, SHARON L

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,787

Applicant(s)

SIMARD ET AL.

Examiner

Sharon Hurt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-11 and 18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/17/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's amendment to the Specification filed July 17, 2006 has been acknowledged. The amendments to Claims 18-22 and 24 have been acknowledged. Newly added Claims filed July 17, 2006 has been acknowledged. Claims 3-6 and 12-17 have been withdrawn. Claims 1-2, 7-11 and 18-28 are pending. Claims 18 and 19 have been canceled as per applicant's remarks (page 15, Conclusion).

Response to Arguments

Rejections Withdrawn

The rejection of Claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** pursuant applicant's amendment.

The rejection of Claim 20 under 35 U.S.C. 102(b) as being anticipated by Moyer et al. (US Patent No. 5,212,057) is withdrawn pursuant applicant's amendment.

Rejections Maintained

The rejection of claims 1-2, 7-11 and 18-20 under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent Application No. 09/781,124) and Thomson et al. (The Journal of Immunology, 1998, Vol. 160, pages 1717-1723) is **maintained**. Applicant's arguments filed July 17, 2006 have been fully considered but they are not persuasive.

Applicant argues that "Hooper does not teach nor suggest polypeptides or immunogenic compositions comprised of polypeptides". Thomson et al. teaches immunogenic compositions

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comprised of polyproteins. Thomson et al. teaches “polyepitope” or “polytope” protein, which is defined as more than one peptide which is made as a result of a single event and not cleaved.

Applicant argues that “the combination of Hooper and Thomson does not teach or suggest polyproteins, or immunogenic compositions comprised of polyproteins, all elements of claims 1-2, 7-11, 18-20 and new claims 27-28”. The relevant teaching is to put the individual proteins or peptides together into a polyprotein. Hooper teaches preferred comments of the polyprotein and Thomson teaches combining into polyprotein.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. in view of Thomson et al. as applied to claims 1-2, 7-11 and 18-20 above, and further in view of Curiel et al. **is maintained**. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that “the deficiencies of Hooper and Thomson are not remedial by Curiel”. Curiel et al teaches that “coupling of the virus or virus component to the polycation via a biotin-protein bridge, preferably a streptavidin-bridge” (column 19, lines 12-13). Curiel teaches the limitation of claims 20 and 21.

Applicant argues that “the deficiencies of Hooper and Thomson are not remedial by Rutter”. Applicant argues that “Rutter does not teach or suggest all the elements of claim 22”. Hooper et al. in view of Thomson et al. teach immunogenic compositions comprising proteins of

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variola major and/or vaccinia. Rutter et al. teaches the vaccine can comprise a nucleic acid vaccine wherein the administration of the nucleic acid vaccine can comprise use of an agent to facilitate delivery of the vaccine, wherein the agent can be a polypeptide, peptide, polysaccharide conjugate, liposome, lipid, etc. (paragraph 040).

Applicant argues that “the deficiencies of Hooper and Thomson are not remedial by Newton”. Applicant argues that “Newton does not teach or suggest all the elements of claim 23. The teachings of Hooper et al. and Thomson et al. are set forth *supra*. Newton et al. teaches about proteins connected by a peptide linker and the fusion protein containing the spacer and linker was the least cytotoxic (Abstract and page 545, 1st paragraph).

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt
November 13, 2006


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